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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/760,380 01/16/01 BELLEAU

B IAF-1/2 C11

024999 HM12/1101  
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EXAMINER

MCKENZIE, T

ART UNIT

PAPER NUMBER

1624

DATE MAILED:

11/01/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/760,380

Applicant(s)

BELLEAU ET AL.

Examiner

Thomas McKenzie Ph.D.

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-7,9-12,14,16-20 and 22-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-7,9-12,14,16-20 and 22-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 08/040163.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. This action is in response to an application filed on 1/16/01. There are twenty claims pending and under consideration. Claims 1-3, 5-7, 9-12, 14, 16-20, and 22-25 are process of making claims. This is the first action on the merits. The application concerns some 1,3-oxathiolanes.

#### ***Priority***

2. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78). The Examiner suggest adding "This is a continuation of Application No. 08/468,329, filed 6/6/95, now US Patent 6,175,008, which is a division of Application No. 08/040,163, filed 3/29/93, now US Patent 5,466,806" should be added to the first sentence of the specification.

#### ***Claim Objections***

3. Claims 5, 6, 9, 14, 16, 22, and 23 are objected to because of the following informalities: they all depend upon presently cancelled claims. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter

which applicant regards as the invention. The phrase "purine or pyrimidine base or an analogue or derivative thereof" is indefinite on three grounds. Firstly, does the "purine or pyrimidine base" include only the heterocycles found in DNA or RNA? Must the "purine or pyrimidine base" be naturally occurring? Is the phrase limited to the two non-substituted heterocycles? Secondly, Webster's New World Dictionary defines analogous as "similar or comparable in some respects". How similar or comparable must a group be covered by this claim for R<sub>2</sub>. Must the radical be a 1,3-diazine? Are different fusion points of the purine analogue permitted? Must the pyrimidine analogue have two nitrogen atoms or be six-membered? Thirdly, Webster's New World Dictionary defines derivative as "a substance derived from ... another substance by chemical change", and "substitution of one or more elements or radicals for one or more constituents of the original substance" has occurred. All implying that new chemical bonds have formed. Since we do not know the reagents or the conditions of these reactions, there is no way of determining the structures of the claimed "derivatives".

5. Claims 1, 2, 3, 5, 10-12, 14, 16-20, and 22 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the reaction intermediates (XIII), (IX), or (XV) with a purine or pyrimidine

containing reagent to make compounds (I). Applicants' Scheme 1 on page 13 makes clear that such a step is an essential part of the overall process of converting  $R_wOCH_2CHO$  to compound I.

6. Claims 2, 3, 5-7, 9, 11, 12, 14, 16-20, and 22-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The independent claims 1 and 10 require  $R_2$  to be a purine or pyrimidine. Only the first two formulas in line 23, page 54 of claim 2 are pyrimidines. Only the left hand formula, line 17, page 55 and the right hand formula, line 1, page 56 of claim 2 are purines. Only the first three formulas in line 16, page 56 of claim 3 are pyrimidines. Only the right hand formula, line 19, page 56 and the middle formula, line 1, page 57 of claim 3 are purines. Similarly, only the first two formulas in line 1, page 60 of claim 11 are pyrimidines. Only the left hand formula, line 19, page 60 and the right hand formula, line 2, page 61 of claim 11 are purines. Only the first three formulas in line 19, page 61 of claim 12 are pyrimidines. Only the right hand formula, line 1, and the middle formula, line 2, page 62 of claim 12 are purines. There is no antecedent basis for the other ring formulas in the rejected claims.

7. Claims 1-3, 5-7, 9-12, 14, 16-20 and 22-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The word “esters” in the second line of claims 1 and 10 is indefinite. What are the structures of these compounds?

8. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The word “thioaryl” in line 13, page 55 is indefinite. It is not clear if the bond from the thioaryl group is from the sulfur or the aryl. If the inventors intend the group HSR-, Examiner suggests the word “mercaptoaryl”. If they intend the group RS-, then the word “aryllthio” is appropriate. Either choice must be supported by the specification.

9. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase “aromatic acyl group” in line 3, page 58 is indefinite for two reasons. Firstly, aromatic might mean hydrocarbons like benzene. It could also include aromatic five and six-membered heterocycles like thiophene and pyridine. Are there any limitations to the size of this group? Secondly, the accepted meaning of the term “acyl” is “any acid

substituent with the OH group removed". The term acyl is indefinite. Does this embrace the acids of sulfur and phosphorus? How is the acyl group attached? Is it through the central atom of the acid group or through some other carbon atom?

10. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "silylated pyrimidine or purine base or analogue thereof" in line 15, page 58 is indefinite for three reasons. Firstly, silane is the molecule  $\text{SiH}_4$  and literally, a silylated compound would contain the radical  $-\text{SiH}_3$ , which is probably not what Applicants intend. Secondly, a broad reading of this term would include silicon attached to the carbon atoms of the pyrimidine or purines and silicon attached to remote side chains of such heterocycles. If that were Applicants' intended meaning, then enablement questions would be raised. Thirdly, the issue of what analogs are claimed was discussed above.

11. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "Lewis acid" in line 16, page 58 is indefinite. This phrase is not defined in the specification and the only working example of such a catalyst is the strong Lewis acid iodotrimethylsilane. Is

the weak Lewis acid  $\text{ZnCl}_2$  or the weaker still Lewis acid  $\text{MgCl}_2$  covered by this term? A proton meets the definition of a Lewis acid. Are protic acids included?

***Double Patenting***

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 5-7, 9-12, 14, 16-20 and 22-25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over



claims 1-10 of U.S. Patent No. 6,175,008. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to the same overall process. The present claims 1 and 10 are a synthesis of formula (I) from mercaptoacetaldehyde. Applicants' dependant claims add limitations concerning solvent catalysts, and nature of the introduced heterocyclic group. Claim 1 of U.S. Patent No. 6,175,008 requires use of mercaptoacetaldehyde to make an intermediate. Claim 7 of U.S. Patent No. 6,175,008 adds the heterocycle coupling, and claim 10 of U.S. Patent No. 6,175,008 completes the synthesis of formula (I). Thus, all elements of Applicants claimed process are present, even though the claim construction is quite different.

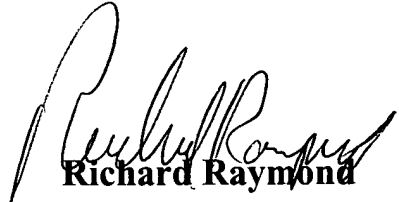
***Allowable Subject Matter***

13. Claims 1-3, 5-7, 9-12, 14, 16-20 and 22-25 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action. The following is a statement of reasons for the indication of allowable subject matter: Applicants claims are patentable over Belleau ('806) because the present claims are drawn to synthesis of the hydroxymethyl compounds not the protected hydroxymethyl compounds of this reference. Applicants' claims are patentable over Goodyear ('709), which does not teach or claim mercaptoacetaldehyde as starting material. Applicants' claims are

patenable over Painter ('004), which claims mercaptoacetic acid not mercaptoacetaldehyde as starting material.

***Conclusion***

14. Please direct any inquiry concerning this communication or earlier communications from the Examiner to Thomas C McKenzie, Ph. D. whose telephone number is (703) 308-9806. The FAX number for the Examiner is (703) 746-3152. The Examiner is available from 8:30 to 5:30, Monday through Friday. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mukund Shah can be reached on (703) 308-4716. Please direct general inquiries or any inquiry relating to the status of this application to the receptionist whose telephone number is (703) 308-1235.

  
**Richard Raymond**  
**Primary Patent Examiner**  
**Art Unit 1624**

TCMcK  
October 25, 2001

